

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization International Bureau



(43) International Publication Date
4 November 2004 (04.11.2004)

PCT

(10) International Publication Number
WO 2004/093726 A2

(51) International Patent Classification⁷:

A61F

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(21) International Application Number:

PCT/US2004/011614

(22) International Filing Date: 16 April 2004 (16.04.2004)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
10/418,483 18 April 2003 (18.04.2003) US

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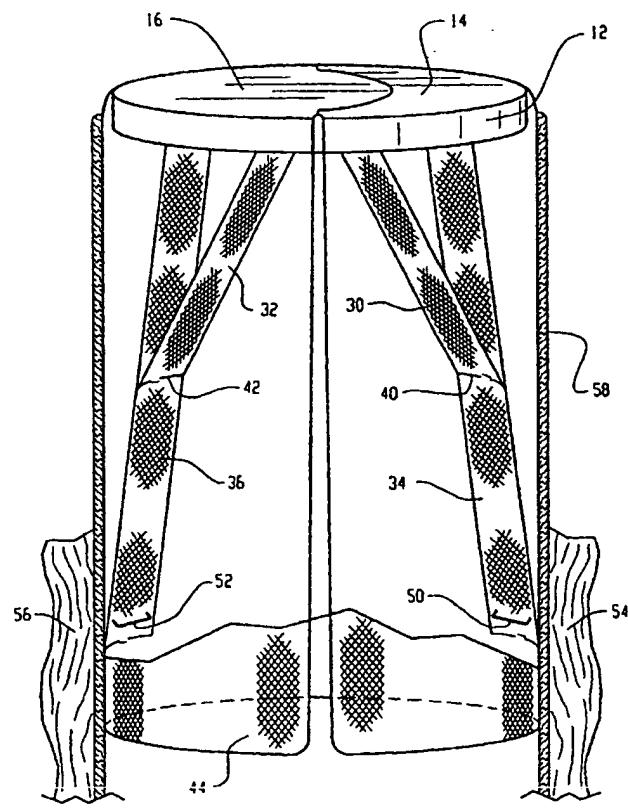
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(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

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(54) Title: REPLACEMENT MITRAL VALVE



(57) Abstract: A sewing ring (12) has a diameter commensurate with a diameter of a removed mitral valve. Skirts (46, 48) of mesh or net material extend downward from the sewing ring and line the walls of an associated vessel (58). Basal chordae simulating structures (34, 36) in the form of elongated strips of mesh or netting, rods, or the like extend from the skirt to an underside of each of two valve leaflets (14, 16). Marginal chordae simulating structures (30, 32) extend between each leaflet and the basal chordae simulating structure. The sewing ring (12) is stitched to an open end of a vessel and inner ends of the basal chordae simulating structure are stitched or stapled (50, 52) to associated papillary musculature (54, 56). In this manner, the papillary muscles assist in controlling the timing and control of the mitral valve.

WO 2004/093726 A2



Published:

— without international search report and to be republished upon receipt of that report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

REPLACEMENT MITRAL VALVE

Background of the Invention

The present invention relates to replacement valves for the circulatory system. It finds particular application in conjunction with mitral valves for human hearts and will be 5 described with particular reference thereto.

Heretofore, various styles of flow operated check valves have been utilized as replacement heart valves. One prior art heart valve includes a ball and valve seat arrangement which limits blood flow to a single direction. A cage 10 surrounding the ball and attached to a sewing ring around the valve seat limits movement of the ball away from the valve seat and natural blood flow.

In another prior design, a tilting or pivotal disk is mounted in the valve seat. Flow in one direction causes the 15 disk to tilt perpendicular to the seat, allowing blood flow. Pressure in the other direction presses the disk valve closed.

In another mechanical valve, a pair of flexible leaflets close the opening between the sewing ring. The leaflets are configured to flex in one direction with flow, 20 permitting blood flow in that direction. Pressure in the opposite direction presses the leaflets together into a sealing relationship.

Bioprosthetic valves have also been utilized. For example, an aortic valve from a pig has been mounted in the 25 sewing ring and used as a replacement mitral valve. However, this aortic valve has three leaflets; whereas, the human mitral

- 2 -

valve has two. Further, the cross-section of the leaflets in the bioprosthetic valve is different from those in humans.

All of these valves work based on pressure differential. However, the human mitral valve operates with muscular assistance. Marginal and basal chordae extend from a lower surface of each leaflet to the papillary muscles. This muscle assists in valve operation. After a valve replacement with any of the above-discussed replacement valves, the papillary muscle no longer provides this assistance function.

10 The present invention overcomes the above-referenced problems and others.

Summary of the Invention

In accordance with one aspect of the present invention, a replacement cardiac valve is provided. The valve 15 includes an annular sewing ring and first and second leaflets closing a region inside of the sewing ring to define a valve. Elongated structures extend from an underside of each leaflet away from the sewing ring. The elongated structures have an attachment region adapted to be attached to a papillary muscle.

20 In accordance with another aspect of the present invention, a mitral valve is provided. An annular sewing ring defines an opening. A cylindrical mesh construction extends downward from the sewing ring. A pair of leaflets define a valve structure connected across the opening of the sewing ring. 25 A synthetic basal chordae means is connected between an outer portion of each leaflet and the cylindrical mesh construction. A synthetic marginal chordae means is connected between each leaflet adjacent an inner edge of each leaflet where the leaflets meet and the synthetic basal chordae means.

30 In accordance with another aspect of the present invention, a method of installing a replacement heart valve which includes a sewing ring, valve leaflets, an anchoring skirt attached to the sewing ring, and a plurality of structures which mimic basal and marginal chordae connected between the leaflets 35 and the skirt is provided. The method includes rolling or folding each skirt portion up towards the sewing ring. The sewing ring is positioned in surrounding tubular vascular

- 3 -

structure where the replacement mitral valve is to be installed no matter the surgical removal procedure. The sewing ring is sewn into the cavity. The leaflets are opened and where the leaflets open, the skirt is unrolled or unfolded along with the 5 chordae mimicking structures. With the leaflets still open, the chordae mimicking structures and the surrounding skirt are attached to papillary musculature.

One advantage of the present invention is that it mimics the human mitral valve more accurately.

10 Another advantage of the present invention resides in its ease of installation using conventional surgical techniques.

Still further advantages of the present invention will become apparent to those of ordinary skill in the art upon 15 reading and understanding the following detailed description of the preferred embodiments.

Brief Description of the Drawings

The invention may take form in various components and arrangements of components, and in various steps and 20 arrangements of steps. The drawings are only for purposes of illustrating a preferred embodiment and are not to be construed as limiting the invention.

FIGURE 1 is a top view of a replacement mitral valve in accordance with the present invention;

25 FIGURE 2 is a side view of the valve of FIGURE 1;

FIGURE 3 is a perspective view of the valve of FIGURES 1 and 2 with the artificial chordae structure on one side of the valve removed for simplicity of illustration;

30 FIGURE 4 is a perspective view similar to FIGURE 3 of an alternate embodiment.

Detailed Description of the Preferred Embodiments

With reference to FIGURE 1, a replacement mitral valve 10 includes a sewing ring 12 around its periphery. The sewing ring is of conventional construction and of a diameter 35 sized to the patient. The sewing ring is sewn to the annular

- 4 -

vasculature structure surrounding the location of the mitral valve to hold the replacement valve in position. A pair of leaflets 14, 16 span the opening defined by the sewing ring. The leaflets can be constructed of biologically compatible synthetic materials or of bioprosthetic materials. For example, the leaflets can be constructed from bovine pericardium.

With reference to FIGURES 2 and 3, an arc 20 of inner or marginal attachment points is defined adjacent an inner edge adjacent the opening of one of the leaflets 14 and a similar arc 10 of attachment points 22 defined on the other leaflet 16. Analogously, outer arcs 24, 26 of outer or basal attachment points are defined on each leaflet. These attachment points are selected substantially in accordance with the attachment points of the marginal and basal chordae of a healthy mitral valve.

15 In the illustrated embodiment, a strip of mesh or netting 30, 32 is attached along the marginal attachment points and strip of basal mesh or netting 34, 36 is attached to the leaflets along the basal attachment points. The marginal mesh or netting sections 30, 32 are attached to the basal mesh or 20 netting sections 34 at an attachment point 40, 42 about mid-way along the basal mesh or netting section 34, 36, respectively. Outer, semi-cylindrical mesh sections 44, 46 extend from the sewing ring along an interior of the associated vessel.

Between the attachment point 40, 42 and a terminal 25 end of the basal mesh or strip sections, a stitch or staple 50, 52 connects the strip or mesh sections to a papillary muscle 54, 56. In this manner, contractions of the papillary muscle act through the mesh or netting sections 30, 32, 34, 36 to pull on the leaflets analogous to natural chordae.

30 For installation, the side curtains 46, 48 are rolled up inward, rolling the mesh strips 30, 32, 34, 36 inside. The sewing ring is positioned in a vessel 58 and stitched into place as is conventional in the mitral valve replacement surgery. The surgeon then manually opens the valve 10 and reaches through, 35 unrolling the side curtains. The surgeon then reaches through the open valve to stitch or staple the basal mesh netting and

- 5 -

the side curtains to the papillary muscles 54, 56. The design is compatible with any of the currently used surgical techniques for diseased mitral valves.

With reference to FIGURE 4, the replacement chordae 5 may take the form of rods or single fibers 60. As yet another alternative, bioprosthetic chordae can be utilized.

- 6 -

Having thus described the preferred embodiment, the invention is now claimed to be:

1. A replacement cardiac valve comprising:
an annular sewing ring (12);
first and second leaflets (14, 16) closing a region
inside the sewing ring to define a valve (10);

5 elongated structures (30, 32, 34, 36, 60) extending
from an underside of each leaflet away from the sewing ring and
having an attachment region adapted to be attached to a
papillary muscle (54, 56).

2. The valve as set forth in claim 1 further
including:

5 a second elongated structure (30, 32, 60) extending
from the underside of each leaflet and connecting with the first
elongated structure (34, 36, 60).

3. The valve as set forth in claim 2 wherein the
first and second elongated structures are made of at least one
of:

5 mesh,
netting,
rods,
strings,
fibers, and,
biocompatible chords.

4. The valve as set forth in claim 2 wherein the
second elongated structures are connected to the leaflets along
an arc (20, 22, 24, 26) adjacent an inner edge of each leaflet
at which the leaflets meet.

5. The valve as set forth in claim 4 wherein the
first elongated structures (34, 36) are connected to each
leaflet in an arc (24, 26) between the inner elongated structure
(30, 32) and the sewing ring (12).

- 7 -

6. The valve as set forth in claim 2 further including:

a pair of semi-cylindrical mesh curtains (44, 46) extending downward from the sewing ring.

7. The valve as set forth in claim 6 wherein the first elongated structures (34, 36) are connected (50, 52) with the mesh curtains (44, 46).

8. The valve as set forth in claim 1 further including:

a mesh structure (44, 46) extending downward from the sewing ring (12).

9. The valve as set forth in claim 7 wherein the first elongated structure (34, 36, 60) is connected to the mesh structure (44, 46).

10. The valve as set forth in claim 9 further including:

5 a second elongated structure (30, 32, 60) connected between the first elongated structure at a point mid-way between the leaflet (14, 16) and the connection of the first elongated structure with the mesh structure, the second elongated structure further being connected with a corresponding leaflet adjacent an inner edge of the leaflet where the leaflets meet in a closed configuration.

11. A mitral valve (10) comprising:

an annular sewing ring (12) which defines an opening; a cylindrical mesh (44, 46) construction extending downward from the sewing ring;

5 a pair of leaflets (14, 16) defining a valve structure connected across the opening of the sewing ring;

a synthetic basal chordae means (34, 36, 60) connected between an outer portion of each leaflet and the cylindrical mesh construction;

- 8 -

10 a synthetic marginal chordae means (30, 32, 60) connected between each leaflet adjacent an inner edge of each leaflet where the leaflets meet and the synthetic basal chordae means (34, 36, 60).

12. The mitral valve as set forth in claim 11 wherein the cylindrical mesh construction includes a pair of semi-cylindrical sections (44, 46).

13. The mitral valve as set forth in claim 11 wherein the synthetic basal and marginal chordae means include one of:

5 mesh,
netting,
rods,
strings,
fibers, and
biocompatible chords.

14. A method of installing a replacement heart valve which includes a sewing ring (12), valve leaflets (14, 16), an anchoring skirt (44, 46) attached to the sewing ring, and a plurality of structures (30, 32, 34, 36, 60) which 5 mimic basal and marginal chordae connected between the leaflets and the skirt, the method comprising:

rolling or folding each skirt portion (44, 46) up toward the sewing ring (12);

10 positioning the sewing ring (12) in a surrounding tubular vessel structure (58) where the replacement mitral valve is to be installed;

sewing the sewing ring (12) into the surrounding vessel structure (58);

opening the leaflets (14, 16);

15 with the leaflets open, unrolling or unfolding the skirt (44, 46) along with the chordae mimicking structures (30, 32, 34, 36, 60);

- 9 -

with the leaflets still open, attaching (54, 56) the
chordae mimicking structures and the surrounding skirt to
20 papillary musculature (54, 56).

1/3

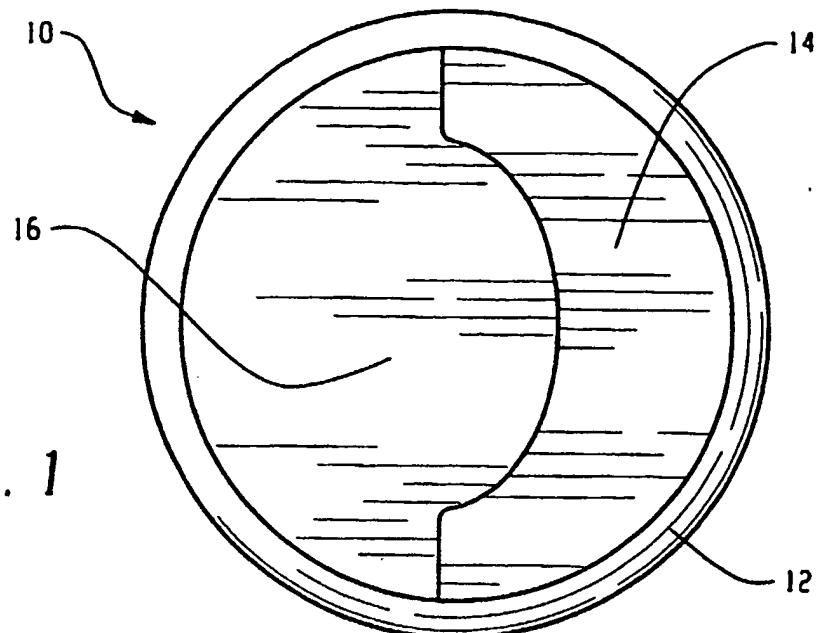


Fig. 1

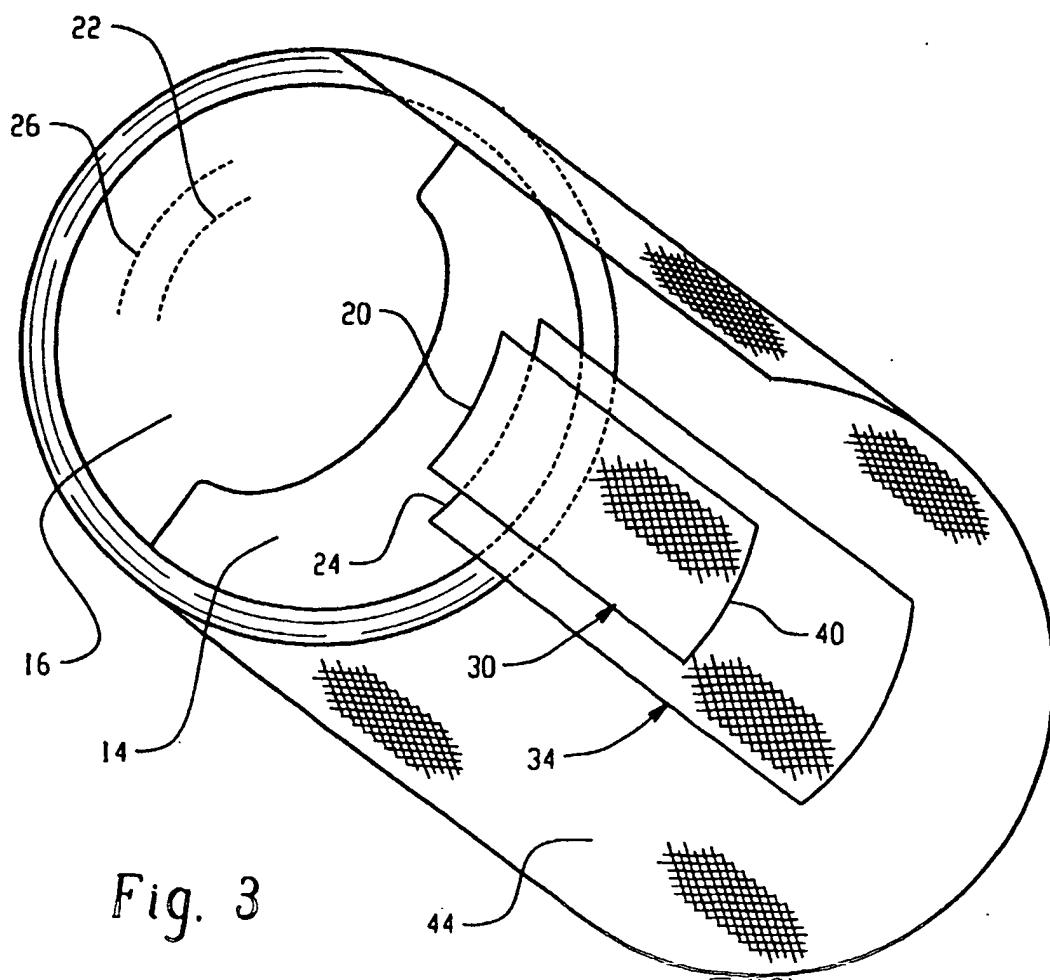


Fig. 3

2/3

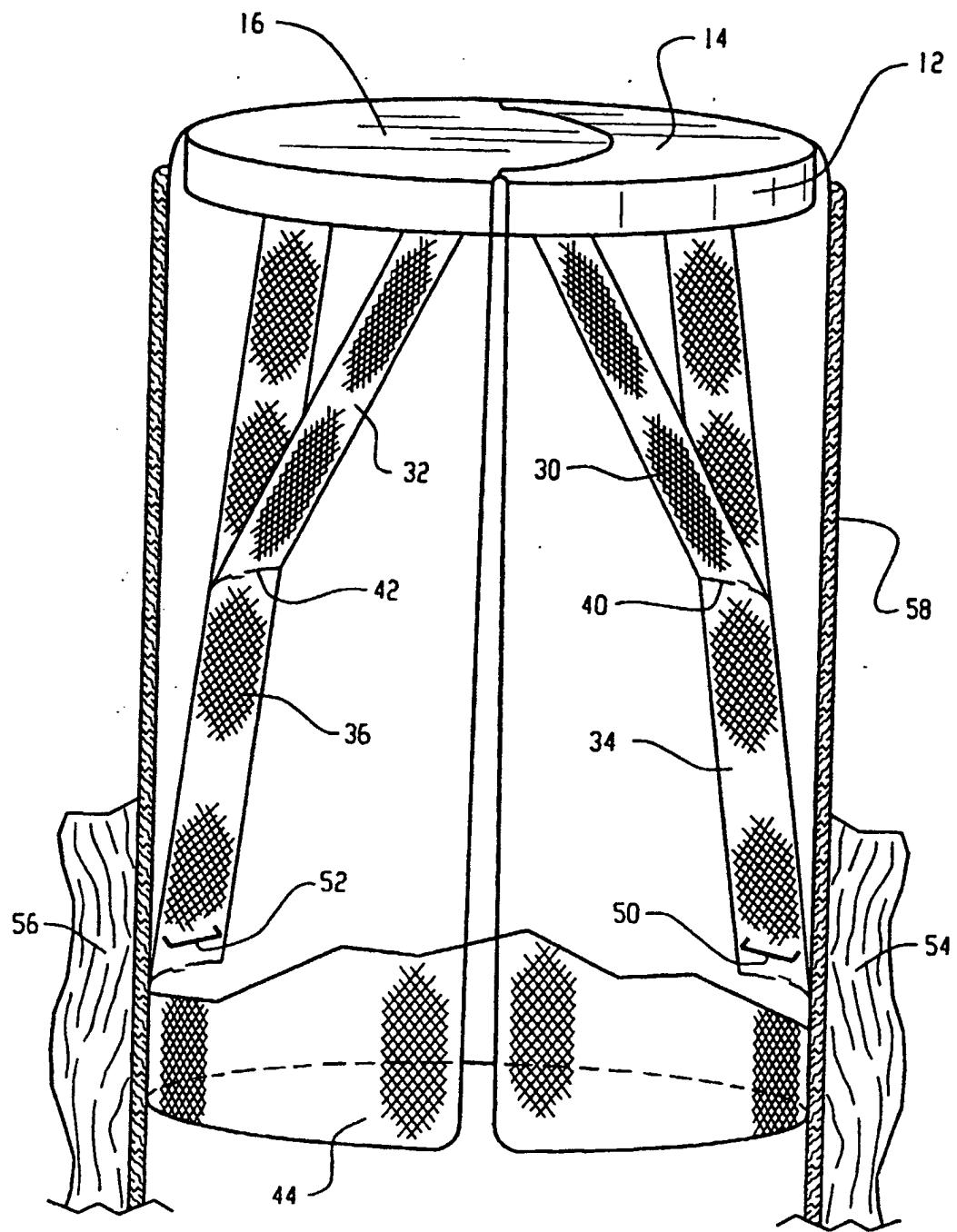


Fig. 2

3/3

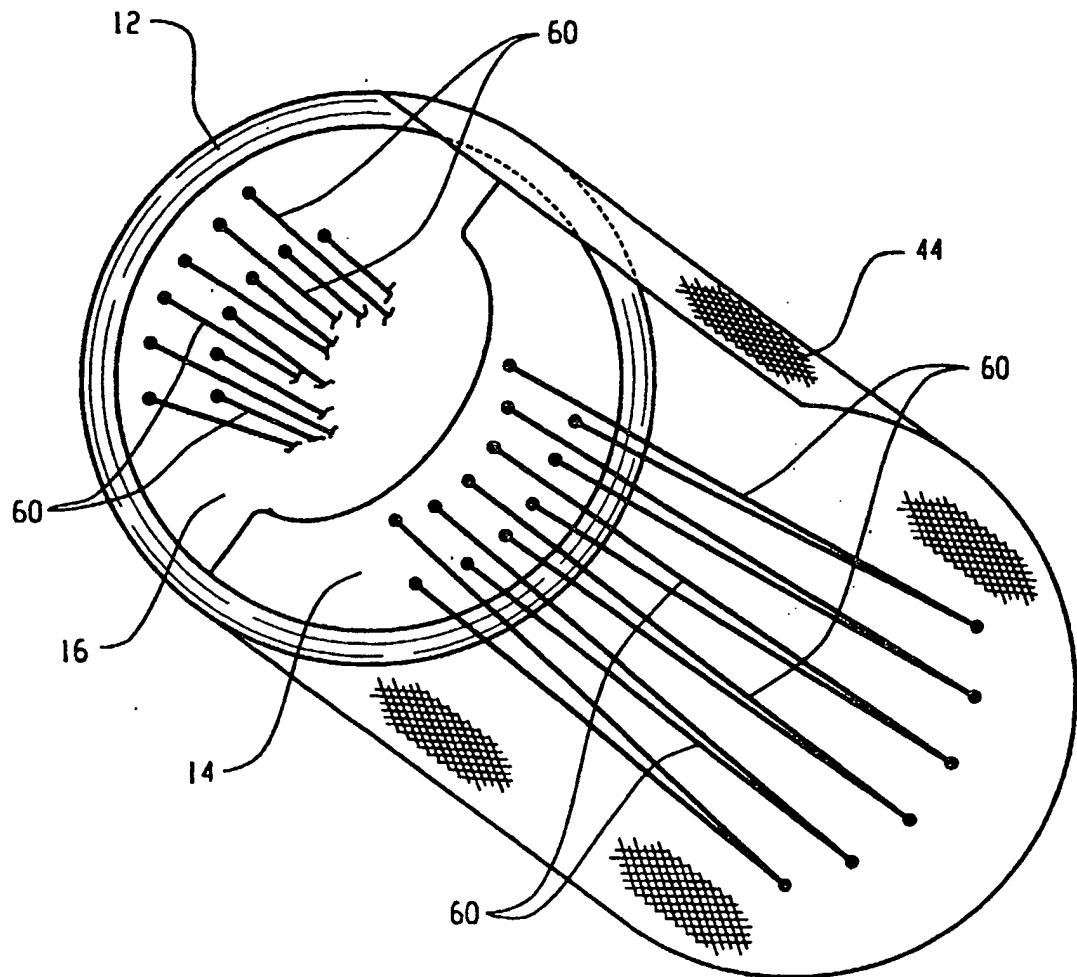


Fig. 4